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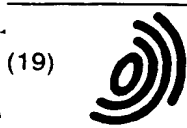
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(54) Hand-held non-contact tonometer

(57) A hand-held non contact tonometer includes a piston (30) having a transparent plane parallel window (31) normal to a measurement axis (20) of the tonometer along which the piston (30) travels to discharge a fluid pulse without interfering with optical alignment functions of the instrument. In a first embodiment an alignment guidance system utilizing a concave mirror (50) and a

target source (52) in a plane containing the center of curvature of the concave mirror (50) present an alignment image to the patient for guiding self-alignment. An infra-red light source (60) at the focal point of the concave mirror (50) irradiates the concave mirror (50) so that a collimated beam is reflected along the measurement axis and focused by an objective lens.

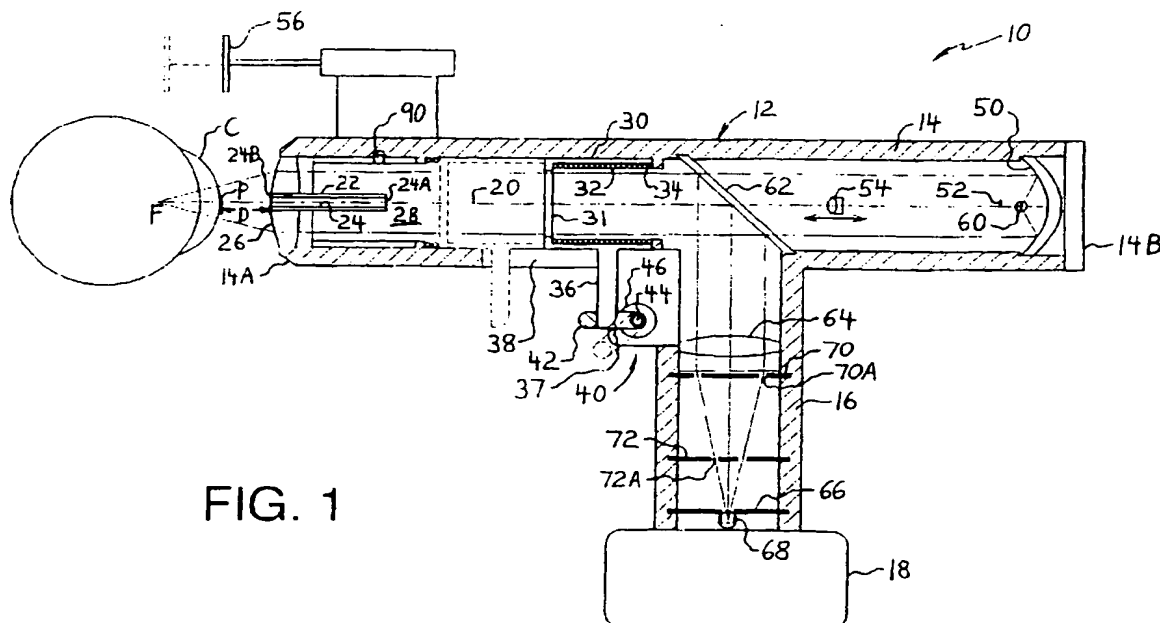


FIG. 1

Description

[0001] The present invention relates to the field of ophthalmic instruments, and more particularly to hand-held non-contact tonometers intended for "at home" self-testing by patients and office use by general medical practitioners.

[0002] Ophthalmologists and optometrists use non-contact tonometers to screen patients for elevated intraocular pressure associated with glaucoma. In the therapeutic care of glaucoma patients, ophthalmologists are confronted with the nearly impossible objective of assuring intraocular pressure control during the long time intervals between patient visits. Around-the-clock intraocular pressure monitoring studies cast serious doubt upon the relevance of sporadic observations in assessment of intraocular pressure control. Many medical doctors have expressed the need for simple and inexpensive non-contact tonometric instrumentation that could be used by patients at home, especially patients who have exhibited nerve tissue loss. Also, it is recognized that a simple and inexpensive non-contact tonometer designed for office use by general medical practitioners could improve chances for early diagnosis.

[0003] Hand-held tonometers of the "contact" variety are well known, as exemplified by U.S. Patent Nos. 4,192,317; 4,622,459; 4,747,296; and 5,174,292. For obvious reasons, these contact instruments are not suitable for self-measurement. Moreover, an operator's skill in testing can have a significant impact upon measurement results, thus rendering these instruments poorly suited for use by general medical practitioners. Patient discomfort is also a drawback of direct contact tonometers.

[0004] U.S. Patent No. 4,724,843 describes a portable non-contact tonometer that includes a carrying case 102 for housing a pump used to generate a fluid pulse, and a detachable hand-held unit 100 connected to the pump by a flexible connection line 104 enclosing a fluid conduit. The described non-contact tonometer precludes self-measurement because an operator other than the patient is required for alignment of the hand-held unit relative to the eye. In addition, the instrument itself is complex and expensive to manufacture.

[0005] It is therefore an object of the present invention to provide a non-contact tonometer that is suitable for home use by a patient. Portability, hand-held alignment, guidance in self-alignment, low cost, and readily understandable measurement output are desirable characteristics of the present invention for meeting the stated object.

[0006] The above object is achieved by a non-contact tonometer as defined in claim 1.

[0007] It is yet a further object of the present invention to provide an alignment guidance system for an ophthalmic instrument such as a tonometer that enables a patient to align the instrument in three-dimensions relative to an eye to be tested for self-testing purposes.

[0008] This object is achieved by an alignment guidance system as defined in claim 16.

[0009] The hand-held non-contact tonometer according to a first embodiment of the present invention generally comprises a measurement axis along which a fluid discharge tube extends for discharging a fluid pulse toward the eye. The fluid discharge tube communicates with a fluid plenum that is subject to rapid volume decrease and pressure increase by a piston biased for movement along the measurement axis from a loaded position to an unloaded position. The piston itself includes a transparent plane parallel window normal to the measurement axis for transmitting collimated target and passive alignment light.

[0010] A patient is guided in self-alignment of the measurement axis and distancing the fluid discharge tube relative to a corneal pole by an alignment guidance system presenting a visible alignment image to a patient. The alignment guidance system includes a concave mirror facing the eye, and a configured target source originating at the measurement axis and residing in a plane normal to the measurement axis containing the center of curvature of the concave mirror. Divergent light from the target source is reflected by the concave mirror to form an inverted and reverted image of the target source about the measurement axis when alignment is achieved, thus appearing to the patient as a predetermined configuration centered on the measurement axis.

[0011] A passive alignment system is preferably incorporated into the tonometer to generate a signal indicating that three-dimensional alignment has been achieved for activating an electro-mechanical trigger mechanism to release the piston. An infra-red light source positioned at a focal point of the concave mirror is masked on one side to emit divergent rays toward the concave mirror, which reflects the incident light as a collimated beam along the measurement axis toward the eye. Light is focused at the front focal point of an objective lens. When the focal point coincides with the center of curvature of the cornea upon proper alignment, light is corneally retro-reflected through the system and diverted by a beam splitter through a lens focusing the light at a pinhole detector. A pair of masks having annular cut-outs prevent light from reaching the pinhole detector unless criteria for three-dimensional alignment are met.

[0012] Corneal applanation is detected according to known reflectance principles using obliquely incident light and a detector on opposite sides of the measurement axis to provide an applanation signal. A pressure sensor is arranged to monitor pressure within the fluid plenum and provide a corresponding pressure signal. The applanation signal and pressure signal are then evaluated to determine intraocular pressure, and one of three color-coded light-emitting diodes is illuminated based on the range of intracular pressures -- safe, borderline, or elevated -- into which the measured intraoc-

ular pressure falls.

[0013] The hand-held non-contact tonometer according to the second embodiment of the present invention is generally similar to that of the first embodiment, however the alignment guidance system, including the concave mirror, is removed and a target source is positioned remotely from the measurement axis to enable an operator to view through an eyepiece located along the measurement axis opposite from the objective lens. A visible spectral component of the retro-reflected target source light passes through a dichroic mirror on the measurement axis for focusing by the eyepiece, while an infra-red spectral component of the light is diverted by the dichroic mirror to a masked detector for passively confirming alignment. A digital readout is preferred to directly report the measured intraocular pressure to the operating medical practitioner.

[0014] The nature and mode of operation of the present invention will now be more fully described in the following detailed description of the preferred embodiments taken with the accompanying drawing figures, in which:

Fig. 1 is a schematic cross-sectional side view of a hand-held non-contact tonometer formed in accordance with a first embodiment of the present invention intended for patient home use;

Fig. 2 is schematic top plan view of the hand-held non-contact tonometer shown in Fig. 1;

Fig. 3 is a schematic block diagram of electronic circuitry of the present invention;

Fig. 4A is an enlarged view showing a self-luminous alignment target of the hand-held non-contact tonometer shown in Figs. 1 and 2;

Fig. 4B is a representation of an alignment image as it would appear to a patient upon achieving proper alignment for the target configuration shown in Fig. 4A;

Fig. 5A is an enlarged view showing an alternative alignment target configuration for use in the hand-held non-contact tonometer shown in Figs. 1 and 2;

Fig. 5B is a representation of an alignment image as it would appear to a patient upon achieving proper alignment for the target configuration shown in Fig. 5A;

Fig. 6A is an enlarged view showing another alternative alignment target configuration for use in the hand-held non-contact tonometer shown in Figs. 1 and 2;

Fig. 6B is a representation of an alignment image as it would appear to a patient upon achieving proper alignment for the target configuration shown in Fig. 6A;

Fig. 7 is a schematic cross-sectional side view of a hand-held non-contact tonometer formed in accordance with a second embodiment of the present invention intended for office use by general medical practitioners; and

Fig. 8 is schematic top plan view of the hand-held non-contact tonometer shown in Fig. 7.

[0015] Reference is directed initially to Figs. 1 and 2 of the drawings, wherein a hand-held non-contact tonometer formed in accordance with a first embodiment of the present invention is shown and designated generally by the reference numeral 10. Tonometer 10 is intended for home use by glaucoma patients for regularly monitoring intraocular pressure between visits to a supervising physician.

[0016] Tonometer 10 comprises a hollow housing 12 including a main tube 14 having a front end 14A and a rear end 14B, and a stem portion 16 joining with main tube 14 between front end 14A and rear end 14B. Housing 12 can be conveniently formed as a two-piece precision molding of mating halves designed with protrusions and recesses at various locations for mounting internal optical, mechanical and electrical components of tonometer 10. It will be appreciated that the configuration of housing 12 facilitates hand-held positioning of tonometer 10, since stem portion 16 provides a "handle" that a user can grasp. A battery pack 18 is situated at a bottom end of stem portion 16 for providing electric power to tonometer 10 without hindering portability, however AC power is a viable alternative or addition. It is contemplated to provide a wire frame stand (not shown) for stationary mounting of tonometer 10 on a table, if desired. Housing 12 is preferably adapted for mounting a flapper device (not shown) near front end 14A used to check instrument alignment and calibration in the field.

[0017] As with prior art non-contact tonometers, hand-held non-contact tonometer 10 of the present invention functions by directing a fluid pulse at cornea C to flatten or "applanate" a predetermined surface area of the cornea, monitoring a corresponding plenum pressure associated with the fluid pulse, and correlating the plenum pressure to intraocular pressure. Consequently, a measurement axis 20 along which the fluid pulse is directed is defined by a fluid discharge tube 22 having an axially extending fluid discharge passage 24 therethrough. Fluid discharge tube 22 is mounted at the front end 14A of housing main tube 14 by an objective lens 26 such that an entry end 24A of fluid discharge passage 24 resides in direct flow communication with a fluid plenum 28 provided in main tube 14. An exit end 24B of fluid discharge passage 24 is substantially flush with an outer surface of objective lens 26. Proper alignment of measurement axis 20 with corneal pole P, and proper location of exit end 24B at a predetermined firing distance D from corneal pole P, typically 11 mm, are necessary for measurement. Alignment of measurement axis 20 with corneal pole P can be thought of as alignment in the X and Y dimensions, while locating exit end 24B at a suitable firing distance D can be thought of as alignment in the Z dimension.

[0018] A piston 30 is mounted in main tube 14 for movement along measurement axis 20 between a load-

ed position, shown in solid line in Figs. 1 and 2, and an unloaded position, shown in broken line in Figs. 1 and 2. Piston 30 includes a transparent plane parallel window 31 normal to measurement axis 20 preferably formed of optical grade glass or optical grade plastic. Piston 30 is biased for movement from its loaded position to its unloaded position by a spring 32 bearing against an internal step 34 in main tube 14. A magnetic biasing means could also be employed. A trigger arm 36 connected to piston 30 extends through an elongated slot 38 in main tube 14 for enabling manual cocking or loading of piston 30 against the urging of spring 32. An electro-mechanical trigger mechanism 40 is housed adjacent an underside of main tube 14 and/or a front side of stem portion 16 for receiving and holding trigger arm 36 when piston 30 is in its loaded position. By way of non-limiting example, trigger mechanism is shown as including an L-shaped gate member 42 mounted for rotation about an axis defined by pivot pin 44 and biased by a torsion spring (not shown) to normally reside in the position shown in Fig. 2. A distal leg of gate member 42 blocks trigger arm 36 to hold piston 30 in its loaded position against the urging of spring 32. An automatic rotational drive means 46, such as a rotary solenoid or motor, is operably connected to drive gate member 42 in a counter-clockwise angular direction to remove the distal leg of the gate member from blocking engagement with trigger arm 36 to release piston 30. Trigger arm 36 includes an arcuate surface 37 used during manual cocking or loading of piston 30 for urging gate member 42 to pivot slightly against its torsional bias to allow the trigger arm to move behind the gate member. The trigger mechanism described at present is meant to serve as an illustrative example of a possible electro-mechanical trigger mechanism, and it is acknowledged that many alternative electro-mechanical trigger mechanisms are conceivable by those of ordinary skill in the art. Such alternative trigger mechanisms are considered to be electro-mechanical trigger means under the claimed invention. It will be appreciated that the manually cocked piston also saves space and cost, however a fully automated return means for moving the piston to its loaded position can also be used without straying from the present invention.

[0019] Tonometer 10 according to the first embodiment is provided with an alignment guidance system that produces an alignment image visible to the eye being measured to guide the patient/user in three-dimensional (X, Y, and Z) self-alignment relative to the eye. The alignment guidance system includes a concave mirror 50 centered on measurement axis 20 near rear end 14B of housing main tube 14 with its reflecting surface facing the eye, and a small self-luminous target 52 located in the plane containing the center of curvature of concave mirror 50. As shown in Fig. 4A, target 52 preferably comprises two orthogonal arms having a vertex coincident with measurement axis 20. Thus, the eye sees the target 52 itself, and an inverted and reverted

image of the target formed by concave mirror 50. If there is XY alignment of corneal pole P with measurement axis 20, the alignment image appears as a completed cross to the patient, as shown for example in Fig. 4B. Reference numeral 52' in Fig. 4B indicates the portion of the viewed alignment image formed by concave mirror 50. If XY alignment is not achieved, the inverted and reverted portion 52' will appear displaced from the position shown in Fig. 4B and the alignment image will not appear as a cross. Of course, other configurations of target 52 are possible, including but not limited to an inverted T-shaped target (Fig. 5A) producing an alignment image appearing as a cross upon proper XY alignment (Fig. 5B), and a V-shaped target (Fig. 6A) producing an alignment image in the form of an X upon proper XY alignment (Fig. 6B). The focus condition of the alignment image as it appears to the user provides an indication of Z alignment status, with a focused alignment image indicating proper firing distance. To accommodate for different refractive vision characteristics among patients, a small compensating lens 54 is preferably mounted on measurement axis 20 between the eye and target 52. The axial position of compensating lens 54 can be adjusted for a particular patient by a supervising physician, as indicated by the double arrow in Fig. 1. Finally, a telescoping stabilizer 56 mounted atop main tube 14 engages the patient's forehead to facilitate Z dimension self-alignment.

[0020] While the patient is visually guided to align tonometer 10 by hand, a passive opto-electronic monitoring system determines when three-dimensional alignment criteria have been met and transmits a signal to trigger mechanism 40 to release trigger arm 36. For this purpose, a small light source 60 is located on measurement axis 20 at the focal point of concave mirror 50. Light source 60 emits light outside the visible spectrum, preferably infra-red light, and is masked on the side facing the eye so that only the full aperture of concave mirror 50 is irradiated. The infra-red light is reflected by concave mirror 50 as a collimated beam travelling along measurement axis 20 toward the eye. The collimated infra-red beam passes through a beam splitter 62 and piston window 31 before being focused at focal point F by objective lens 26. When focal point F coincides with the cornea's local center of curvature, all rays are retro-reflected back through objective lens 26 and piston window 31 to beam splitter 62. Upon reaching beam splitter 62, the retro-reflected infra-red light is reflected by the beam splitter in a direction orthogonal to measurement axis 20. The redirected infra-red light is focused by a focusing lens 64 through a pinhole occluder 66 to a light-sensitive detector 68. Interposed between focusing lens 64 and detector 68 are two masks 70 and 72 having respective annular cut-outs 70A and 72A of decreasing diameter in the direction of travel toward detector 68. In a manner analogous to Scheiner disk focus techniques, the masks 70 and 72 preclude rays from reaching apertured detector 68 unless three-dimensional alignment

criteria have been satisfied. Upon XYZ alignment, a voltage spike is generated by detector 68.

[0021] Referring also now to the block diagram of Fig. 3, the signal from detector 68 is amplified and processed under the control of a central processing unit 73 to determine the existence of a voltage spike indicating three-dimensional alignment. When alignment has been established, a signal is transmitted to solenoid driver 74 to energize rotational drive means 46 of trigger mechanism 40, thereby releasing piston 30 instantaneously. Piston 30 is forced along measurement axis 20 toward its unloaded position such that the volume of plenum 28 is rapidly decreased and the pressure within the plenum is rapidly increased, causing a fluid pulse to be discharged from the fluid discharge passage 24 of fluid discharge tube 22.

[0022] Tonometer 10 is equipped with applanation detection means, shown in Fig. 2, for monitoring corneal deformation caused by the fluid pulse and generating an applanation signal indicating the occurrence of corneal applanation. More specifically, an infra-red emitter 80 and collimating lens 82 direct an obliquely incident beam of light toward cornea C in the vicinity of corneal pole P, and a collector lens 84 and apertured detector 86 are positioned laterally and symmetrically opposite emitter 80 and collimating lens 82 relative to measurement axis 20. When cornea C is in its natural convex state, obliquely incident collimated light from emitter 80 is fanned out upon reflection by the curved surface of the cornea, thus resulting in a very low intensity signal at detector 86. The fluid pulse deforms cornea C from its original convex state, through an applanated state, to a concave state. When the corneal surface approximates a flat surface, the incident collimated light is reflected in a collimated manner from the corneal surface toward collector lens 84. Consequently, the intensity signal at detector 86 rises sharply during applanation and then falls off sharply as the cornea becomes concave. Consequently, a usually well-defined peak signal from detector 86 coincides with the moment of applanation. Other optical reflectance schemes are known in the tonometric art for determining applanation, with U.S. Patent No. 3,538,754 by the present inventor being incorporated herein by reference for its teachings with regard to applanation detection. For sake of compactness, two fused bundles of very low numerical aperture optical fibers having distal ends angled to intersect at measurement axis 20 can be substituted for collimating lens 82 and collector lens 84.

[0023] A pressure sensor 90, for example a pressure transducer or the like, is placed within fluid plenum 28 to measure plenum pressure as the fluid pulse is generated. Pressure sensor 90 produces a signal proportional in magnitude to the fluid pressure in plenum 28.

[0024] The applanation and pressure signals are processed to find the plenum pressure at the moment of applanation. In this regard, tonometer 10 operates in a manner similar to non-contact tonometers of the prior

art, such as the XPERT NCT available from Reichert Ophthalmic Instruments. A regression equation stored in memory 75 during clinical calibration of tonometer 10 allows the plenum pressure to be correlated to intraocular pressure measured in millimeters of mercury (mm-Hg). The intraocular pressure measurement result is reported to the patient in a manner that allows the result to be readily understood by the patient. The measurement result is preferably reported to the patient by illuminating one of three colored light-emitting diodes 101, 102, or 103 placed either externally on housing 12, as depicted in Fig. 2, or mounted internally for viewing through main tube 14. A green LED 101 is preferred for indicating an intraocular pressure within a "safe" range from, for example, 7 mmHg to 17 mmHg, an orange or yellow LED 102 is preferred for indicating an intraocular pressure within a "borderline" range as defined and set by the supervising physician depending on the specific needs and condition of the patient, and a red LED 103 is preferred for warning of an intraocular pressure within an "elevated" range above the borderline range. A range selection control 77 for setting the borderline intraocular pressure range is provided internally in tonometer 10 rather than externally to prevent patient adjustment thereof. Before tonometer 10 is issued to a patient, the supervising physician adjusts the borderline range and positions compensating lens 54 according to patient requirements.

[0025] Attention is now directed to Figs. 7 and 8 of the drawings showing a tonometer 110 formed in accordance with a second embodiment of the present invention. Tonometer 110 is intended for office use by a general medical practitioner for early detection of elevated intraocular pressure. Tonometer 110 is similar to tonometer 10 of the first embodiment with respect to its measurement functions of fluid pulse generation, applanation detection, pressure sensing, and signal processing, with identical reference numbers indicating the same elements in each embodiment. Tonometer 110 differs from tonometer 10 of the first embodiment in that the self-alignment system used in the first embodiment is removed to allow an operator to visually perceive alignment directly along measurement axis 20 by looking through main tube 14 from rear end 14B toward the patient's eye.

[0026] In order to accommodate operator viewing, an adjustable focusing eyepiece 111 is provided at rear end 14B of main tube 14. A target source 152 emitting light in the visible and infra-red ranges is physically located in stem portion 116 off of measurement axis 20, and a lens 113 collimates light from target source 152 prior to forward reflection of the light by a beam splitter 115 positioned on measurement axis 20. The target light passes through piston window 31 and is focused at the front focal point F of objective lens 26. When focal point F is coincident with the center of curvature of cornea C, all incident rays are normal to the cornea and thus are retro-reflected by the cornea back through objective lens

26 for travel as a collimated beam along measurement axis 20. The corneally reflected light passes through piston window 31, beam splitter 115, and a dichroic mirror 117. Dichroic mirror 117 transmits visible spectral components of the light for focusing by eyepiece 111, thereby presenting a target image to an operator for assisting in alignment of tonometer 110. A fixed forehead rest 121 is preferably provided for the operator looking through eyepiece 111. Infra-red spectra are reflected by dichroic mirror 117 along a path orthogonal to measurement axis 20 to be used for passive alignment monitoring and trigger activation in the same manner described above in connection with the first embodiment. A digital readout 123, indicated in Fig. 3, is preferably substituted for the color-coded LED range reporting of the first embodiment to display a direct intraocular pressure value as measured by tonometer 110.

[0027] As will be appreciated from the above disclosure, the present invention provides inexpensive, portable, and self-usable tonometric instrumentation for patient home use and inexpensive, portable tonometric instrumentation for use by general physicians and the like. Tonometers 10 and 110 are manually alignable and automatically discharge a fluid pulse upon three-dimensional alignment to take a measurement.

Claims

1. A hand-held non-contact tonometer (10,110) for measuring intraocular pressure of an eye by directing a fluid pulse along a measurement axis (20) to deform the cornea of said eye, characterized in that a piston (30) movable along said measurement axis (20) is provided to generate said fluid pulse, wherein said piston (30) includes a plane parallel window (31) normal to said measurement axis (20) for transmitting light traveling parallel to said measurement axis (20) without optical consequence irrespective of said piston's position along said measurement axis (20).
2. The hand-held non-contact tonometer (10,110) as defined in claim 1, comprising:
 - a fluid discharge tube (22) having a fluid discharge passage (24) aligned on said measurement axis (20), said fluid discharge passage (24) having an entry end (24A) and an exit end (24B);
 - a fluid plenum (28) in flow communication with said entry end (24A) of said fluid discharge passage (24);
 - the piston (30) movable between a loaded position and an unloaded position for increasing pressure within said plenum (28) to discharge a fluid pulse from said exit end (24B) of said fluid discharge passage (24);
3. The hand-held non-contact tonometer (110) as claimed in claim 2, characterized in that, the alignment system is configured as an alignment guidance means for presenting a visible alignment image to a patient for guiding said patient in self-alignment of said measurement axis (20) with a corneal pole (P) of the eye to be tested.
4. The hand-held non-contact tonometer (10) as claimed in claim 2, characterized in that, the alignment system is configured as an opto-electronic alignment monitoring system for generating an alignment signal at the instant X, Y, and Z alignment is achieved.
5. The hand-held non-contact tonometer according to claim 3, further comprising an eyepiece (111) aligned on said measurement axis (20), a target light source (152) off of said measurement axis (20), a collimating lens (113) after said target light source (152) for receiving divergent light from said target light source (152) and forming a collimated beam of light, a beam splitter (115) between said eyepiece (111) and said eye for reflecting said collimated beam along said measurement axis (20) toward said eye, an objective lens (26) for focusing said collimated beam at an external focal point (F), and a dichroic mirror (117) on said measurement axis (20) for receiving corneally reflected light, said dichroic mirror (117) transmitting visible light to said eyepiece (111) and reflecting non-visible light for use by said alignment monitoring system.
6. The hand-held non-contact tonometer according to claim 4, wherein said alignment monitoring system includes a concave mirror (50) having a center of curvature on said measurement axis (20) and a self-luminous target (52) located in a plane containing said center of curvature normal to said measurement axis (20), whereby light from said target (52) is reflected by said concave mirror (52) to form an inverted and reverted image of said target about

said measurement axis (20).

7. The hand-held non-contact tonometer according to claim 6, wherein said target (52) comprises a pair of orthogonal leg portions having a vertex on said measurement axis (20), whereby said alignment image appears as a cross upon X-Y alignment.
8. The hand-held non-contact tonometer according to claim 6, wherein Z alignment of said exit end (24B) of said fluid discharge passage (24) is guided by the focus condition of said alignment image and wherein the alignment monitoring means further includes a correction lens adjustable along said measurement axis to compensate for patient refractive errors in viewing said alignment image.
9. The hand-held non-contact tonometer according to claim 1, further comprising an adjustable stabilizer for engaging the forehead of said patient.
10. The hand-held non-contact tonometer according to claim 9, further comprising a stabilizer for engaging the forehead of an operator.
11. The hand-held non-contact tonometer according to claim 1, further comprising electro-mechanical trigger means for holding said piston (30) in said loaded position and releasing said piston to cause said fluid pulse to be discharged.
12. The hand-held non-contact tonometer according to claim 11, wherein said trigger means automatically releases said piston (30) upon achievement of X-Y alignment of said measurement axis (20) with said corneal pole (P) and Z alignment of said exit end (24B) of said fluid discharge passage (24) at a predetermined firing distance from said corneal pole (P).
13. The hand-held non-contact tonometer according to claim 12, wherein said electro-mechanical trigger means is operatively connected to an opto-electronic alignment monitoring system, wherein said trigger means automatically releases said piston (30) in response to an alignment signal generated by said alignment monitoring system at the instant X, Y, and Z alignment is achieved.
14. The hand-held non-contact tonometer (10) according to claim 4, wherein said opto-electronic alignment monitoring system includes a non-visible light source (60) on said measurement axis (20), a concave mirror (50) facing said eye and having a focal point at said non-visible light source (60) for receiving divergent light from said non-visible light source (60) and reflecting a collimated beam of light toward said eye, an objective lens (26) for focusing said col-

limated beam at an external focal point (F), a beam splitter (62) on said measurement axis (20) between said non-visible light source (60) and said eye for receiving corneally reflected light and diverting said light from said measurement axis (20), a focusing lens (64) for focusing said diverted light, a light-sensitive detector (68) for receiving light from said focusing lens (64), and a pair of masks (70, 72) interposed between said focusing lens (64) and said detector (68) each having an annular cut-out (70A, 72A) for passing light focused on said detector (68) by said focusing lens (64) when XYZ alignment is achieved.

15. The hand-held non-contact tonometer according to claim 2, wherein said reporting means comprises a digital readout for displaying said intraocular pressure value.
16. An alignment guidance system for presenting a visible alignment image to a patient for guiding said patient in self-alignment of an ophthalmic instrument relative to an eye to be tested, said alignment guidance system comprising:
 - a self-luminous fixation target (52) located on a measurement axis (20) of said ophthalmic instrument; and
 - a concave mirror (50) having a center of curvature on said measurement axis (20), said target (52) being located in a plane containing said center of curvature and being normal to said measurement axis (20);
 - whereby light from said target (52) is reflected by said concave mirror (50) to form an inverted and reverted image of said target about said measurement axis (20) when said measurement axis is aligned with a direction of fixation of said eye.
17. The alignment guidance system according to claim 16, wherein said target (52) comprises a pair of orthogonal leg portions having a vertex on said measurement axis (20), whereby said alignment image appears as a cross upon alignment of said measurement axis with said direction of fixation.
18. The alignment guidance system according to claim 42, wherein distance alignment of said ophthalmic instrument relative to said eye is guided by the focus condition of said alignment image.
19. The alignment guidance system according to claim 18, further comprising a correction lens (54) adjustable along said measurement axis (20) to compensate for patient refractive errors in viewing said alignment image.

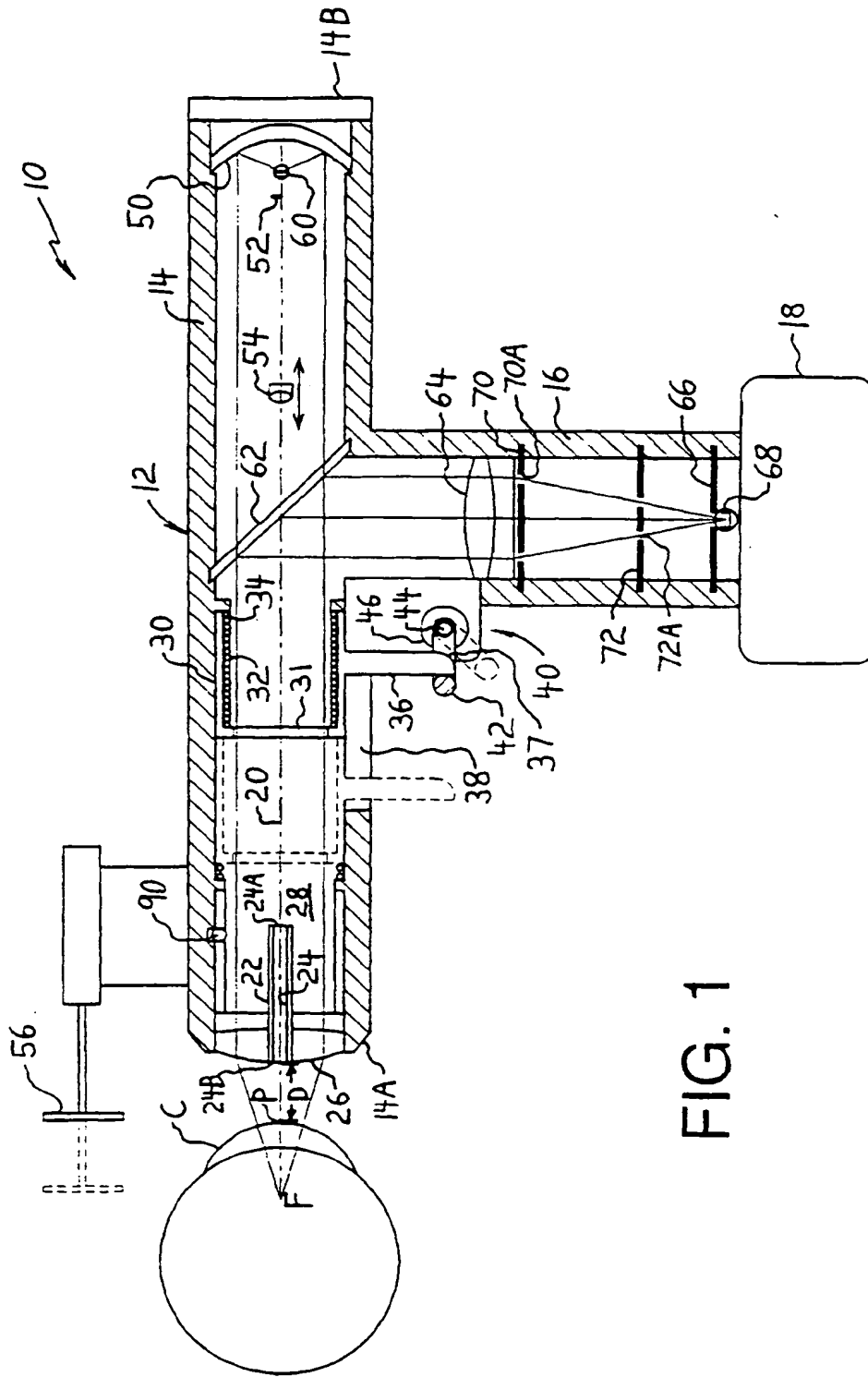


FIG. 1

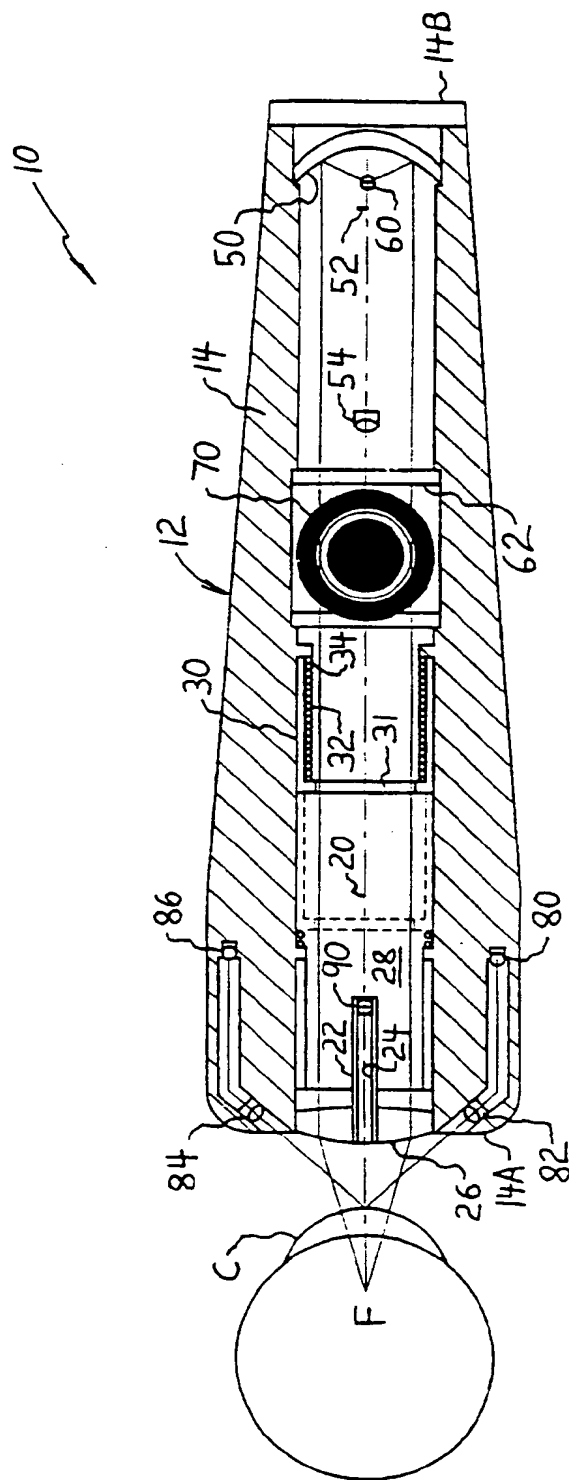


FIG. 2

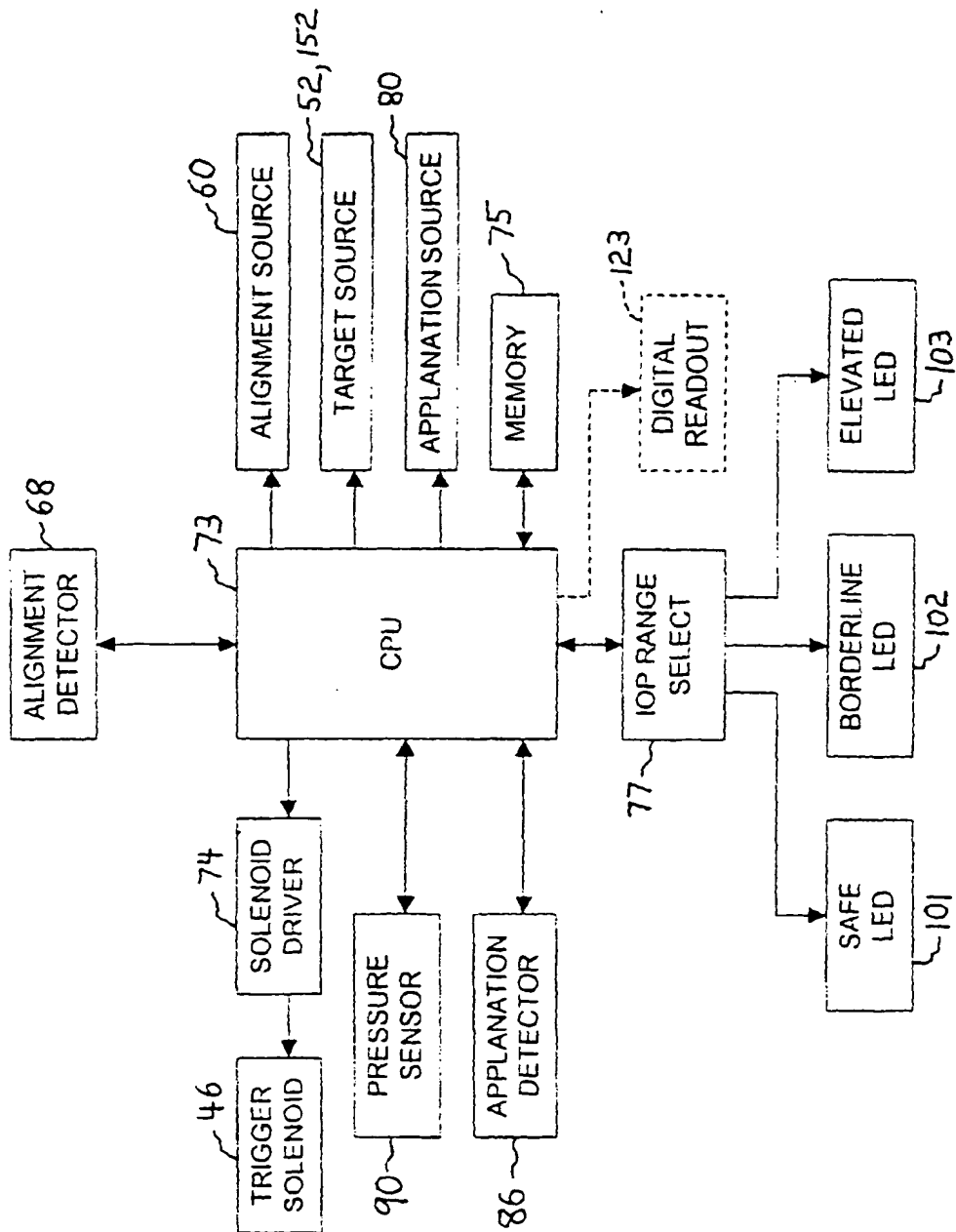


FIG. 3

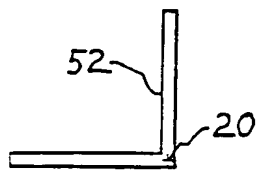


FIG. 4A

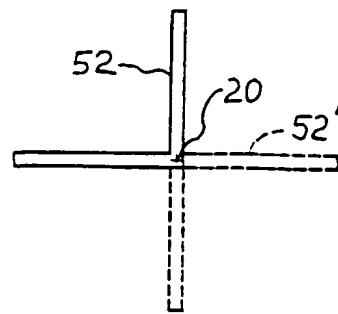


FIG. 4B

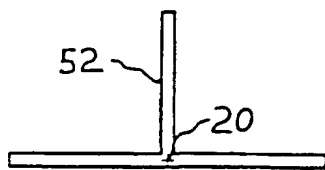


FIG. 5A

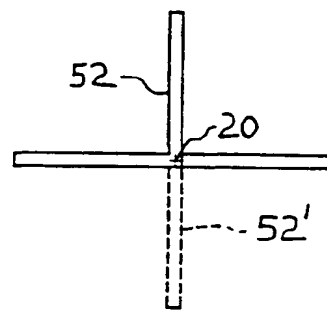


FIG. 5B

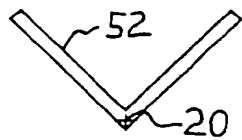


FIG. 6A

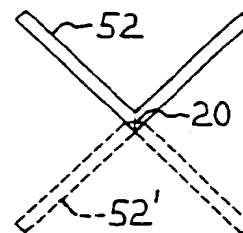


FIG. 6B



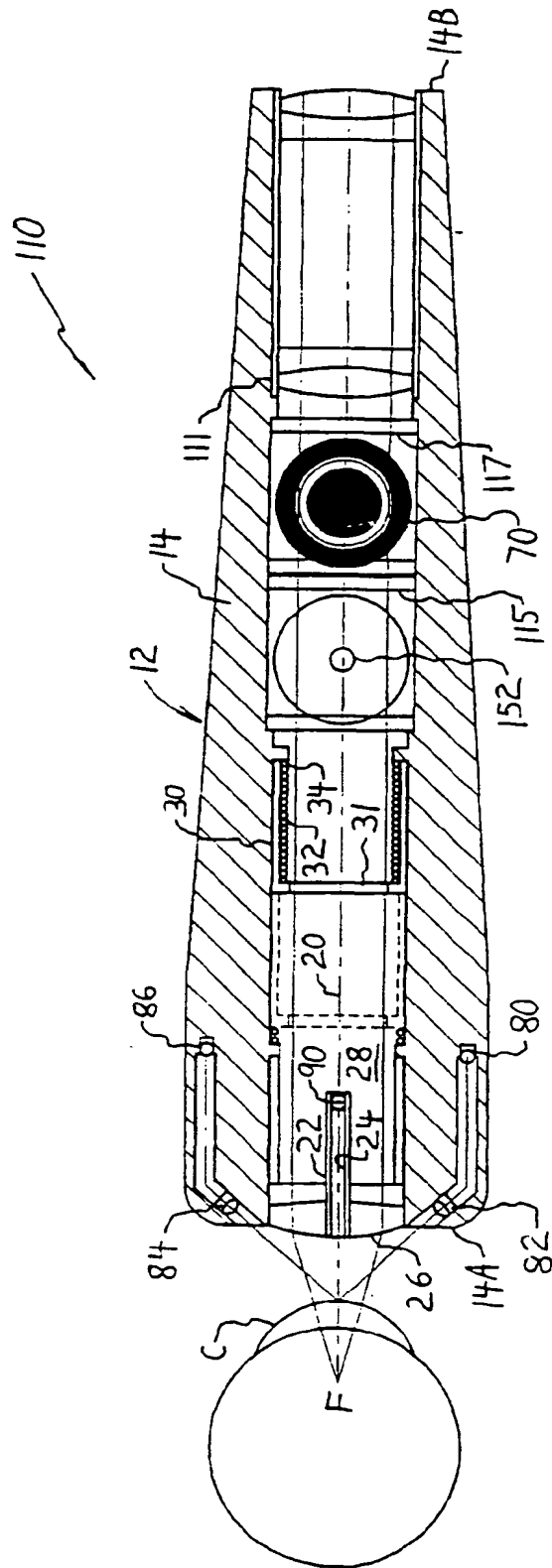


FIG. 8



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(30) Priority: 07.02.2000 US 499837

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(54) Hand-held non-contact tonometer

(57) A hand-held non contact tonometer includes a piston (30) having a transparent plane parallel window (31) normal to a measurement axis (20) of the tonometer along which the piston (30) travels to discharge a fluid pulse without interfering with optical alignment functions of the instrument. In a first embodiment an alignment guidance system utilizing a concave mirror (50) and a

target source (52) in a plane containing the center of curvature of the concave mirror (50) present an alignment image to the patient for guiding self-alignment. An infra-red light source (60) at the focal point of the concave mirror (50) irradiates the concave mirror (50) so that a collimated beam is reflected along the measurement axis and focused by an objective lens.

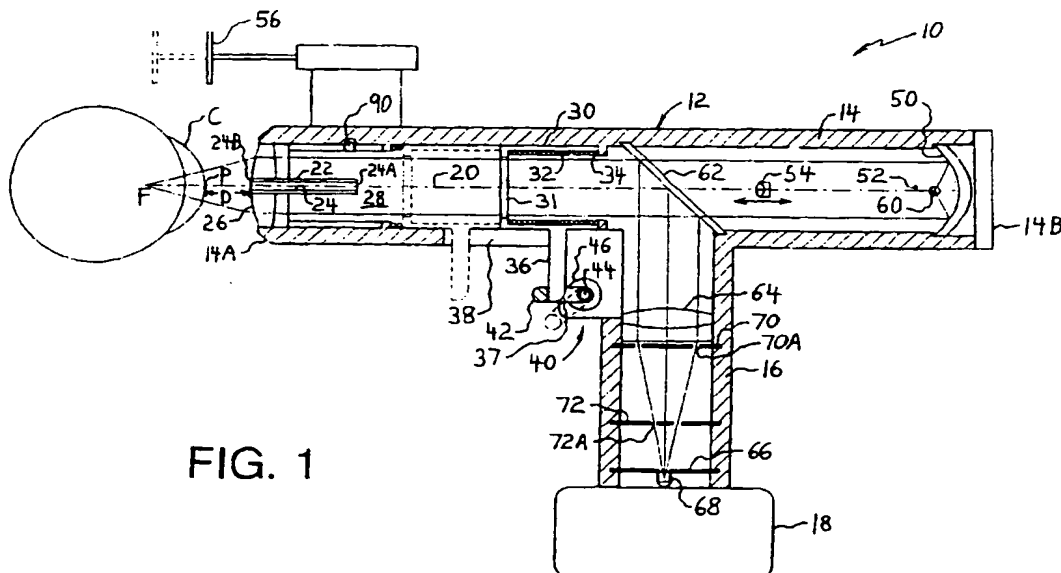


FIG. 1



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EUROPEAN SEARCH REPORT

Application Number
EP 01 10 1473

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
A	US 5 299 573 A (KOBAYASHI KAZUNOBU) 5 April 1994 (1994-04-05) * column 1, line 31 - column 4, line 23; figures 1,2 *	1-4,6, 11-13,15	A61B3/16
A	US 4 817 620 A (KATSURAGI KENJIRO ET AL) 4 April 1989 (1989-04-04) * column 1, line 43 - line 68 * * column 3, line 15 - column 8, line 17; figures 1,6 *	1,2,4-6, 11-13,15	
A	US 5 964 704 A (HAYAFUJI MINEKI) 12 October 1999 (1999-10-12) * column 1, line 54 - column 6, line 15 *	1-5, 11-15	
A	EP 0 209 966 A (FISHER JOHN) 28 January 1987 (1987-01-28) * page 2, line 23 - page 10, line 14 * * page 18, line 15 - page 22, line 20 *	2-5, 7-10,14, 15	
A	PATENT ABSTRACTS OF JAPAN vol. 015, no. 425 (C-0879), 29 October 1991 (1991-10-29) & JP 03 176023 A (CANON INC), 31 July 1991 (1991-07-31) * abstract; figures 1-13 *	1-3,5,7	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61B
A	PATENT ABSTRACTS OF JAPAN vol. 016, no. 118 (C-0922), 25 March 1992 (1992-03-25) & JP 03 289932 A (CANON INC), 19 December 1991 (1991-12-19) * abstract; figures 1-9 * & US 6 131 574 A (KOHAYAKAWA YOSHIMI) 17 October 2000 (2000-10-17) * column 1, line 1 - column 4, line 10; figures 1-9 *	1-6,8, 11-14	
-/--			
The present search report has been drawn up for all claims			
Place of search:		Date of completion of the search	Examiner
THE HAGUE		21 June 2002	Neef, T
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : member of the same patent family, corresponding document X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document	

EPO FORM 1501 (12/16) IP 1400



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Application Number

EP 01 10 1473

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet 8

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-15



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EUROPEAN SEARCH REPORT

Application Number
EP 01 10 1473

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI.7)
A	US 5 094 521 A (JOLSON ALFRED S ET AL) 10 March 1992 (1992-03-10) * figure 5 *	9,10	
			TECHNICAL FIELDS SEARCHED (Int.CI.7)
<p>The present search report has been drawn up for all claims</p>			
Place of search		Date of completion of the search	Examiner
THE HAGUE		21 June 2002	Neef, T
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X particularly relevant if taken alone ✓ particularly relevant if combined with another document of the same category A technological background () non-written disclosure P intermediate document</p> <p>T theory or principle underlying the invention E earlier patent document, but published on, or after the filing date U document cited in the application L document cited for other reasons & member of the same patent family, corresponding document</p>			

EP 01 10 1473 A3 (1992-03-10)



European Patent
Office

**LACK OF UNITY OF INVENTION
SHEET B**

Application Number

EP 01 10 1473

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-15

Hand-held non-contact tonometer for measuring intraocular pressure of an eye.

2. Claims: 16-19

Alignment guidance system for guiding a patient in self-alignment of an ophthalmic instrument relative to an eye to be tested

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 10 1473

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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21-06-2002

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 5299573	A	05-04-1994	JP	5184546 A	27-07-1993
US 4817620	A	04-04-1989	JP	2588881 B2	12-03-1997
			JP	63065842 A	24-03-1988
US 5964704	A	12-10-1999	JP	11019044 A	26-01-1999
EP 0209966	A	28-01-1987	AT	70423 T	15-01-1992
			DE	3682966 D1	30-01-1992
			EP	0209966 A1	28-01-1987
			GB	2175412 A ,B	26-11-1986
			JP	1658911 C	21-04-1992
			JP	3017487 B	08-03-1991
			JP	61272028 A	02-12-1986
			US	4724843 A	16-02-1988
JP 03176023	A	31-07-1991	NONE		
JP 03289932	A	19-12-1991	JP	2886936 B2	26-04-1999
			US	6131574 A	17-10-2000
US 5094521	A	10-03-1992	NONE		